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(12) **Patent:**
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(54) METHOD OF INACTIVATING REPRODUCIBLE FILTERABLE PATHOGENS IN BLOOD PRODUCTS AS WELL AS A METHOD OF PRODUCING BLOOD PRODUCTS

(54) METHODE D'INACTIVATION DE PATHOGENES FILTRABLES DANS LES PRODUITS SANGUINS ET METHODE DE PRODUCTION DE PRODUITS SANGUINS

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ABSTRACT:

ABSTRACT OF THE DISCLOSURE:
A method of inactivating viruses in blood products is described, wherein the blood products are heat-treated in a humid or in a solid state in the presence of inorganic or organic hydroxyl group-containing compounds having an H+dissociation constant of < 10-11 in a concentration of more than 0.05 (5 % by weight) and less than 0.70 (70 % by weight). The hydroxyl group-containing compounds may be water, methanol, or ethanol. The temperature may amount up to 121°C, the heat treatment may last from 1 s to 100 h. The inactivation method may be applied for producing blood products selected from enzymes, proenzymes including coagulation factors, enzyme inhibitors, immunoglobulins, albumin, plasminogen, fibrinogen, fibronectin or plasma, the inactivation destroying any reproducible filterable pathogens that might be present.

CLAIMS: Show all claims

*** Note: Data on abstracts and claims is shown in the official language in which it was submitted.

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Patent Cooperation Treaty (PCT): **No**

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Application No.	Country	Date
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Availability of licence: **N/A**

Language of filing: **English**

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THE EMBODIMENTS OF THE INVENTION IN WHICH AN EXCLUSIVE PROPERTY OR PRIVILEGE IS CLAIMED ARE DEFINED AS FOLLOWS:

1. A method of inactivating viable filterable pathogens in blood products under application of an elevated temperature, characterized in that the blood products, in a solid state, are adjusted to a content of water, methanol or ethanol of more than 0.05 (5 % by weight) and less than 0.70 (70 % by weight) and are treated in a closed container at a temperature ranging from 50 to 121°C, while maintaining the blood products in their solid state and while increasing the partial vapor pressure of water, methanol or ethanol.

2. A method as set forth in claim 1, wherein the blood products are adjusted to a content of water, methanol or ethanol of less than 0.40 (40 % by weight).

3. A method as set forth in claim 1, wherein the blood products are treated with water vapor at a pressure of from 0.1 to 2 bar.

4. A method as set forth in claim 1, wherein said viable filterable pathogens are hepatitis viruses.

5. A method as set forth in claim 1, wherein said viable filterable pathogens are agents capable of transmitting Aids (acquired immune deficiency syndrome).

The invention relates to a method of inactivating viabl filterable pathogens, in particular hepatitis viruses and pathogens which may be able to transmit AIDS (acquired immune deficiency syndrome), in blood products by using an elevated temperature, as well as to a method of producing blood products by using this method.

By blood products, products of human or animal blood or plasma are meant which are intended for a therapeutic, prophylactic or diagnostic use. Such products may contain enzymes, proenzymes including coagulation factors, enzyme inhibitors, immunoglobulins, albumin, plasminogen, fibrinogen, fibronectin or plasma.

There are abundant publications dealing with the thermal inactivation of reproducible filterable pathogens in blood products.

The various methods include:

- heating of the blood products in aqueous solution, if desired, with the addition of virucidal substances,
- heating of the blood products in aqueous solution in the presence of stabilizing agents,
- treating the blood products with organic solvents,
- irradiating the blood products in the solid state,
- heating of the blood products in the dry state.

All these inactivation methods aim at destroying the potential infectivity of the preparations while substantially maintaining their biological activity. Up to now, however, this aim could be achieved only with albumin preparations, i.e. by heating aqueous albumin solutions at a temperature of 60°C for 10 hours, since albumin is considerably more stable towards heat than all other blood

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A method of inactivating viruses in blood products is described, wherein the blood products are heat-treated in a humid or in a solid state in the presence of inorganic or organic hydroxyl group-containing compounds having an H^+-dissociation constant of $< 10^{-11}$ in a concentration of more than 0.05 (5 % by weight) and less than 0.70 (70 % by weight). The hydroxyl group-containing compounds may be water, methanol, or ethanol. The temperature may amount up to 121°C, the heat treatment may last from 1 s to 100 h. The inactivation method may be applied for producing blood products selected from enzymes, proenzymes including coagulation factors, enzyme inhibitors, immunoglobulins, albumin, plasminogen, fibrinogen, fibronectin or plasma, the inactivation destroying any reproducible filterable pathogens that might be present.

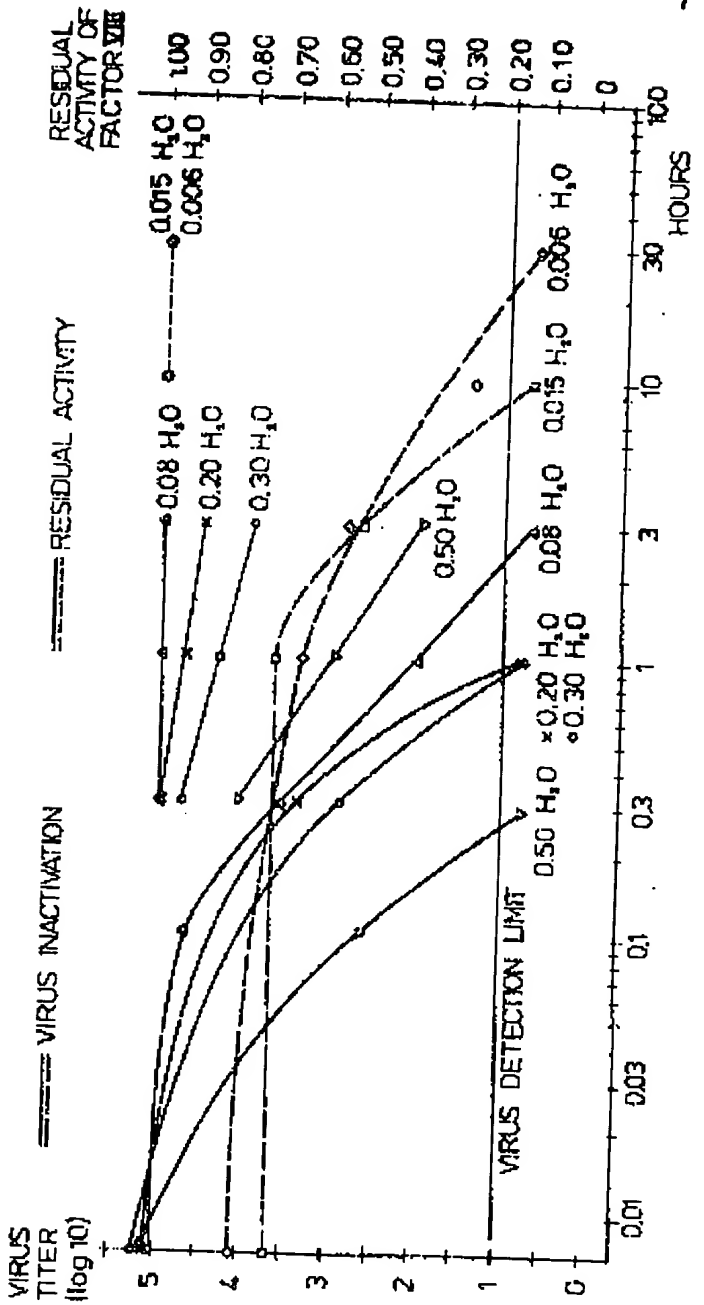

FIG. 1 INACTIVATION OF A MODEL VIRUS (SINDBIS VIRUS) AND RESIDUAL ACTIVITY OF FACTOR VIII WHEN HEATING A FACTOR VIII PREPARATION AT 60°C

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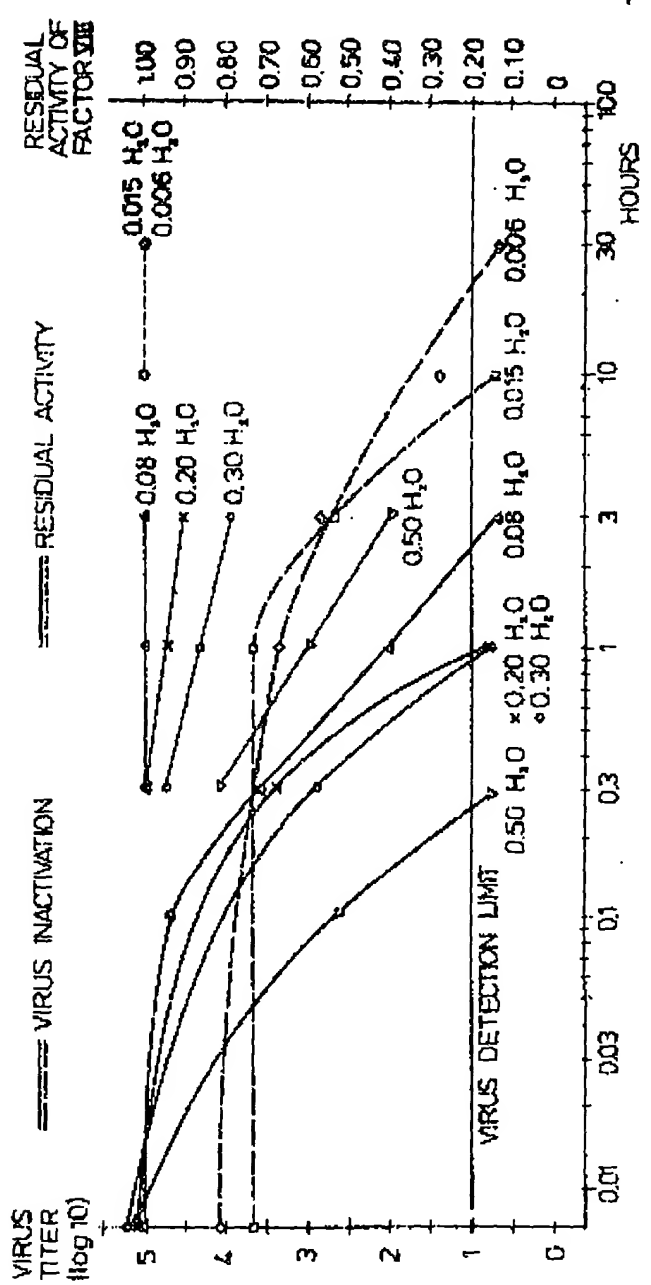

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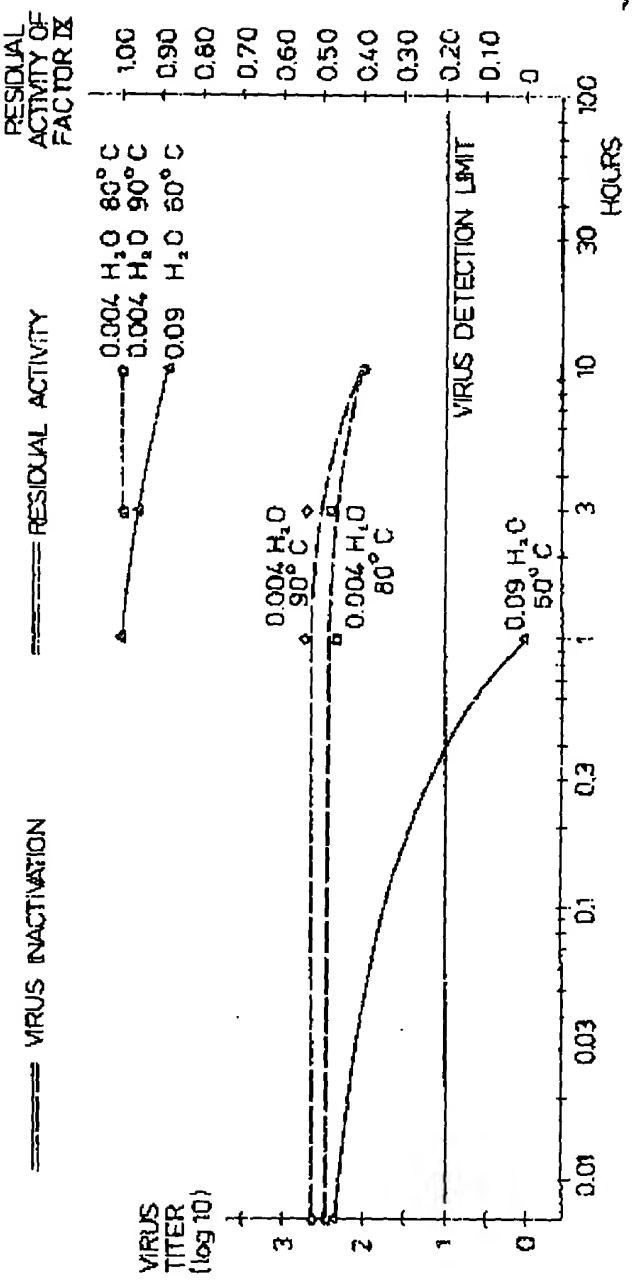

FIG. 2 INACTIVATION OF A MODEL VIRUS (BACTERIOPHAGE T4) AND RESIDUAL ACTIVITY OF FACTOR IX WHEN HEATING A PARTIAL PROTHROMBIN COMPLEX PREPARATION

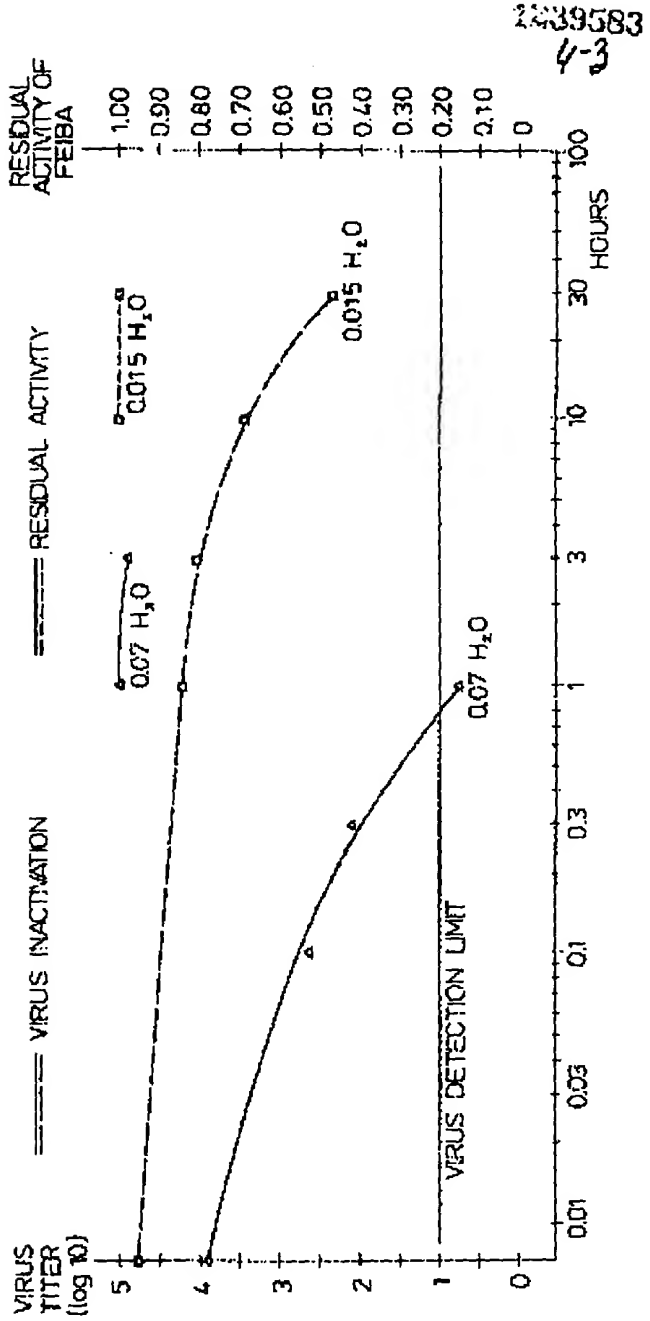

FIG. 3 INACTIVATION OF A MODEL VIRUS (CANINE HEPATITIS VIRUS) AND FEIB-RESIDUAL ACTIVITY WHEN HEATING A FEIBA PREPARATION AT 60°C

FIG. 4